

CLAIMS

We claim:

5 1. A transdermal delivery device for diagnosing infectious disease comprising topical application of a composition comprising antigen and physiologically effective solution.

10 2. The device of Claim 1, wherein the device comprises a material selected from the group consisting of medical tape, medical plaster, gauze, TORII's band, Finn-chamber and Perm-aide S.

15 3. The device of Claim 2, wherein the antigen is derived from mycobacterial species comprising *M. tuberculosis complex*, *M. avium-intracellulare*, *M. kansasii*, *M. fortuitum*, *M. chelonae*, *M. leprae*, *M. africanum*, and *M. microti*.

20 4. The device of Claim 3, wherein the antigen comprises MPB44, MPB45, MPB51, MPB59, MPB64, MPB70, MPB80 or MPB83.

25 5. The device of Claim 1, wherein the physiologically effective solution comprises surfactants, buffers or solvents.

30 6. The device of Claim 5, wherein the physiologically effective solution comprises phosphate buffered solution comprising Tween 20, Tween 40, Tween 60, or Tween 80.

7. The device of Claim 2, wherein the antigen comprises MPB64 and the physiologically effective solution comprises phosphate buffered solution and Tween 80.

35 8. The device of Claim 7, wherein the infectious disease comprises tuberculosis.

9. A method of detecting active disease comprising,
topically applying a transdermal delivery device to
skin, wherein said device comprises an antigen composition;
removing said transdermal delivery device after a
predetermined period of time;
observing the skin for an immune response; and
correlating the presence of the immune response with
active disease.

10. The method of Claim 9, wherein the transdermal
delivery device comprises a material selected from the group
consisting of medical tape, medical plaster, gauze, TORII's band,
Finn-chamber and Permiade S.

11. The method of Claim 9, wherein the antigen
composition comprises a physiologically effective solution;
further comprising antigen derived from mycobacterial species
selected from the group consisting of *M. tuberculosis complex*,
M. avium-intracellulare, *M. kansasii*, *M. fortuitum*, *M. chelonae*,
M. leprae, *M. africanum*, and *M. microti*.

12. The method of Claim 11, wherein the antigen
comprises MPB44, MPB45, MPB51, MPB59, MPB64, MPB70,
MPB80 or MPB83.

13. The method of Claim 11, wherein the physiologically
effective solution comprises surfactants, buffers and solvents.

14. The method of Claim 13, wherein the physiologically
effective solution comprises phosphate buffered solution further
comprising Tween 20, Tween 40, Tween 60, or Tween 80.

15. The method of Claim 11, wherein the antigen
composition comprises MPB64 and phosphate buffered solution
further comprising Tween 80.

16. The method of Claim 15, wherein the active disease comprises tuberculosis.

5 17. An composition for detecting infectious disease comprising,
an antigen, and
a physiologically effective solution for transdermal delivery following topical application.

10 18. The composition of Claim 17, wherein the antigen is derived from mycobacteria.

15 19. The composition of Claim 18, wherein the antigen comprises MPB44, MPB45, MPB51, MPB59, MPB64, MPB70, MPB80 or MPB83.

20 20. The composition of Claim 19, wherein the physiologically effective solution for transdermal delivery comprises surfactants, buffers and solvents.

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